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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/539,664	05/15/2006	Richard John Nighy	IMV-40013	4684
21015	7590	07/31/2008		
PYLE & PIONTEK LLC 221 N. LASALLE STREET, SUITE 2036 CHICAGO, IL 60601			EXAMINER MYERS, JESSICA L	
			ART UNIT 3746	PAPER NUMBER
			MAIL DATE 07/31/2008	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/539,664

**Applicant(s)**

NIGHY ET AL.

**Examiner**

JESSICA L. MYERS

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10/9/07.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 31-61 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 31-61 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 6/14/05 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SE/US)  
Paper No(s)/Mail Date 6/14/05, 5/15/06
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Drawings*

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "first portion" and the "second portion" of the membrane as claimed in claim 31, the "layer of polyamide" and "layer of polyurethane" as claimed in claim 37, the "identification means" and "reader means" as claimed in claim 50, and the "detecting means" as claimed in claim 60 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner,

the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

In Reference to Claim 37

3. Claim 37 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. A membrane having two layers is never shown in applicant's drawings, and it is unclear how the two layers would be assembled or bonded together.

In Reference to Claims 50, 51, and 52

4. Claims 50, 51, and 52 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The identification means and the reader means are not shown in the drawings and it is unclear how the identification means and the reader means would be integrated into the pump as shown. Furthermore, it is unclear how the means would

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function without a power source, or how the information gained from them would be used since no processor is disclosed to process the identification data.

In Reference to Claims 60 and 61

5. Claims 60 and 61 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The detector means is not shown and it is unclear where the detector means would be located in the pump since no room has been made for it in the pumping chamber. . Furthermore, it is unclear how the means would function without a power source, or how the information gained from it would be used since no processor is disclosed to process the data.

***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 31, 48, and 49 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 4,303,376 to Siekmann (Siekmann).

In Reference to Claim 31

Siekmann teaches a disposable pump unit for receiving and metering a predetermined volume of fluid (see figure 3 and 4), the pump comprising a body (body (20)), the body having a surface at which opens the mouth of a cavity (recesses (25 and 26)) formed in the body, an inlet port (in the inlet valve region (34)) for connection with a reservoir of fluid and opening at the body surface adjacent to the mouth of the cavity whereby, when the inlet port is open when the pump is being filled with fluid from the reservoir (see valve operation diagram (figure 6) for operation of pump), fluid can flow from the inlet port into the cavity via the mouth thereof, an outlet port (in the outlet valve region (39)) for the fluid and opening at the body surface, and a fluid flow passageway extending through the body and connecting the cavity to the outlet port; and flexible membrane means (diaphragm (27)) sealingly secured at its periphery to the body surface and having a first portion overlying the cavity and the inlet port (the upper portion of diaphragm as shown in figure 3) and a second portion overlying the outlet port (the lower portion of the diaphragm as shown in figure 3), the flexible membrane means whereat it overlies the inlet and outlet ports being moveable against the ports to close the ports (see figure 3).

In Reference to Claim 48

Siekmann teaches a disposable pump unit according to claim 31 (see the rejection of claim 31 above), wherein the body inlet port is fluid connected to a disposable reservoir (flask or bag (13)) containing fluid to be supplied to the inlet port, so that when the reservoir is empty the combined reservoir and pump unit may be

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disposed of (both the bag (13) and the pump could be disposed of when the reservoir becomes empty).

In Reference to Claim 49

Siekmann teaches a disposable pump according to claim 48 (see the rejection of claim 48 above), including openable closure (clamp (17)) means between the disposable pump unit and the reservoir (see figure 1 and column 4 lines 21-25), so that the reservoir and disposable pump unit may be shipped together while preventing flow of fluid from the reservoir into the disposable pump unit (The clamp could be used to prevent fluid flow while the unit is being transported).

3. Claims 31 and 56 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 5,088,515 to Kamen (Kamen).

In Reference to Claim 31

Kamen teaches a disposable pump unit for receiving and metering a predetermined volume of fluid (see figure 8), the pump comprising a body, the body (housing unit (124)) having a surface at which opens the mouth of a cavity formed in the body (output (62a)), an inlet port (input (61a)) for connection with a reservoir of fluid and opening at the body surface adjacent to the mouth of the cavity whereby, when the inlet port is open when the pump is being filled with fluid from the reservoir, fluid can flow from the inlet port into the cavity via the mouth thereof (see column 7 lines 38-61), an outlet port (output (62b)) for the fluid and opening at the body surface, and a fluid flow passageway extending through the body and connecting the cavity to the outlet port

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(see figure 8); and flexible membrane (membrane sheet (91)) means sealingly secured at its periphery to the body surface and having a first portion overlying the cavity and the inlet port (the upper portion of the membrane as shown in figure 8) and a second portion overlying the outlet port (the lower portion of the membrane as shown in figure 8), the flexible membrane means whereat it overlies the inlet and outlet ports being moveable against the ports to close the ports.

In Reference to Claim 56

Kamen teaches 56. (previously presented) A disposable pump unit according to claim 54, wherein the valve actuator means for the second valve means that is associated with the outlet port includes a stepper motor (see column 4 lines 47-55) operable to variably control the size of the opening through the outlet port to provide a variable flow restriction (The stepper motor would control the flow of the control source gas in figure 8 which in turn would control the valve lift of the inlet and outlet valves.).

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 31-36, 38-41, 44, 46, 53-55, and 57-61 are rejected under 35

U.S.C. 102(e) as being anticipated by U.S. Patent 6,905,314 to Danby (Danby).



In Reference to Claim 31

Danby teaches a disposable pump unit for receiving and metering a predetermined volume of fluid (see figures 3 and 4), the pump comprising a body (rigid shell (33) with upper half (33A) and lower half (33B)), the body having a surface at which opens the mouth of a cavity formed in the body (see the construction of a single pump cell in figures 8A and 8B which give a clearer depiction of how the pump operates than figure 3 which shows multiple pumping cells and flow conduits), an inlet port (connected to valve (47")) for connection with a reservoir of fluid and opening at the body surface adjacent to the mouth of the cavity whereby, when the inlet port is open when the pump is being filled with fluid from the reservoir (see figure 8A and columns 6-7 lines 51-20), fluid can flow from the inlet port into the cavity via the mouth thereof, an outlet port (connected to valve (47")) for the fluid and opening at the body surface, and a fluid flow passageway extending through the body and connecting the cavity to the outlet port; and flexible membrane means (liner (13) composed from two sheets of material (13A and 13B)) sealingly secured at its periphery to the body surface (see column 5 lines 32-35) and having a first portion overlying the cavity and the inlet port (the bottom left portion of the liner (13) as shown in figure 8A covers the cavity and the inlet port (47")) and a second portion overlying the outlet port (the bottom right portion of the liner (13) as shown in figure 8A covers the outlet port (47")), the flexible membrane means whereat it overlies the inlet and outlet ports being moveable against the ports to close the ports (see figures 8A and \*b and also columns 6-7 lines 51-40).

In Reference to Claim 32

Danby teaches a disposable pump unit according to claim 31 (see the rejection of claim 31 above), wherein the first and second portions of the flexible membrane means together comprise an integral flexible membrane (the left and right portions of the membrane as shown in figure 8A together make up liner (13)).

In Reference to Claim 33

Danby teaches a disposable pump unit according to claim 31 (see the rejection of claim 31 above), wherein said first and second portions of the flexible membrane means are separate from one another (the left and right portions of the membrane as shown in figure 8A are spaced from each other in the lateral direction, since the valves are separated from each other, and in that sense they are separate from one another).

In Reference to Claim 34

Danby teaches a disposable pump unit according to claim 31 (see the rejection of claim 31 above), wherein the first portion of the flexible membrane means is substantially non-stretchable and is pre-formed in part to a shape substantially similar to the shape of a surface of the pump cavity (The two sheets (13A and 13B) are welded together to define multiple pump cells, and so each pump cell would be welded so that its shape matches the shape of the cavity, see figure 6) such that, when the pump is operated to pump a metered volume of fluid through the outlet port, the pre-formed part of the flexible membrane means can be urged by an actuating fluid into the pump cavity and into contact with substantially the whole surface of the cavity (see figure 8A and also columns 6-7 lines 51-20) to force from the cavity and through the passageway and outlet port substantially all of the fluid that flowed from the reservoir into the cavity when

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the pump was filled ("the receptacle members [the cavities] (117A and 117B) define the maximum volume of the pump").

In Reference to Claim 35

Danby teaches a disposable pump unit according to claim 34 (see the rejection of claim 34 above), wherein during storage and transportation of the pump the preformed part of the flexible membrane means is adapted to lie flush with the surface of the pump cavity to reduce the susceptibility of the flexible membrane means to damage during transit (The two liners (13A and 13B) are preformed in the sense that they are welded together to form leak-proof pump cells. These preformed welded sections lie flat when they are sandwiched between the upper and lower (33A and 33B) shells of the casing. See figure 6, where the substantially flat portions of the liner are sandwiched between flat portions of the casing.).

In Reference to Claim 36

Danby teaches a disposable pump unit according to claim 31 (see the rejection of claim 31 above), wherein the flexible membrane means comprise a laminate flexible film comprising a layer of substantially non-stretchable polymer and a layer of a heat-weldable polymer (The two layers (13A and 13B) of the liner (13) are made from appropriate polymers (see column 4 lines 8-17) which are welded together).

In Reference to Claim 38

Danby teaches a disposable pump unit according to claim 31 (see the rejection of claim 31 above), including a variable fluid flow restrictor downstream from the cavity

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(the second valve (47")) acts as a variable fluid flow restrictor, since it restricts the flow of fluid leaving the chamber at various times.).

In Reference to Claim 39

Danby teaches a disposable pump unit according to claim 31 (see the rejection of claim 31 above), wherein the body includes a plurality of cavities and associated pluralities of inlet ports (inlets (25) as shown in figure 4), outlet ports (the outlets of pumps cells (17)), passageways (passages (27)) and flexible membrane means (each pump cell has an associated membrane), the disposable pump unit being adapted to be coupled to a pump actuator (high pressure reservoir (75) and lower pressure reservoir (77)) that operates the pump unit to fill at least one cavity from the reservoir while simultaneously pumping fluid out of at least one other cavity (Danby discloses that the cells can be operated by the high and low pressure sources individually, but that it is expensive to do so (see column 8 lines 49-65)).

In Reference to Claim 40

Danby teaches a disposable pump unit according to claim 39 (see the rejection of claim 39 above), including a fluid flow channel (header pump cell (21) connects the outlet ports of the pump cells (17)) interconnecting the outlet ports (see figure 4).

In Reference to Claim 41

Danby teaches a disposable pump unit according to claim 31 (see the rejection of claim 31 above), wherein the body includes a pair of cavities (pump cells (17)) and associated pairs of inlet ports (inlets (25)), outlet ports (the outlets of the pump cells lead to header pump cell (21)), passageways (passageways (27)) and flexible

membrane means (liner (13) is segmented by welding into cells that coincide with the cavities and passageways), the disposable pump unit being adapted to be coupled to a pump actuator (high pressure reservoir (75) and lower pressure reservoir (77)) that operates the pump unit to fill one cavity from the reservoir while simultaneously pumping fluid out of the other cavity (Danby discloses that the cells can be operated by the high and low pressure sources individually, but that it is expensive to do so (see column 8 lines 49-65)).

In Reference to Claim 44

Danby teaches a disposable pump unit according to claim 31 (see the rejection of claim 31 above), wherein the body further has a chamber (mixing chamber (107) shown in figure 1), downstream from the outlet port, for being fluid coupled to a source of diluent and having a diluent inlet whereby pumped fluid exiting the outlet port mixes with diluent in the chamber (See column 10 lines 13-34 which discloses that the mixing chamber allows for the pumped fluid to be mixed with a base fluid such as carbonated water that is held in a base liquid reservoir (108)).

In Reference to Claim 46

Danby teaches a disposable pump unit according to claims 44 (see the rejection of claim 44 above), wherein the body includes an outlet passageway (header pump cell (21)) downstream from the chamber, the outlet passageway including mixing means (the header pump cell (21) is connected to multiple pump chambers, each of which could have a different liquid exiting from it. These liquids would mix in the header pump cell (21) see column 9 lines 40-51).

In Reference to Claim 53

Danby teaches a disposable pump unit according to claim 39 (See the rejection of claim 39 above), wherein each inlet port of the plurality of inlet ports (inlets (25)) is for being fluid coupled to an associated one of a plurality of sources of fluid to be pumped (reservoirs (104) of drink flavorings, see figure 1), the body including passage (passages (27)) means for fluid coupling together the plurality of outlet ports to provide a common outlet (header pump cell (21)) for fluid pumped from the plurality of cavities, so that the disposable pump unit may be operated by the pump actuator to selectively dispense the respective fluids individually or in combination (see column 8 lines 49-65, column 10 lines 13-34, and column 2 lines 24-50).

In Reference to Claim 54

Danby teaches a disposable pump unit according to claim 34 (see the rejection of claim 34 above), including a reusable pump (high pressure reservoir (75) and lower pressure reservoir (77)) actuator releasably coupled to the disposable pump unit body (the high and low pressures are releasably applied, with a low pressure liquid being applied during the intake stroke, and a high pressure liquid being applied during the discharge stroke) with the first and second portions of the flexible membrane means interposed therebetween (the membrane (13) lies between the upper portion (33A) of the casing, which has ports (61) with valves (63) to connect the chambers to the pressure sources, and the lower portion of the cavity (33B)), the pump actuator including means for providing positive and negative actuating fluid pressures on the pre-formed part of the flexible membrane means opposite from the cavity to move the

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preformed part into and out of the body cavity to respectively pump fluid from the cavity and draw fluid into the cavity (see column 6 lines 20-50), and first and second valve means respectively associated with the inlet and outlet ports (valves (47' and 47'') seen in figure 8), each valve means including a valve actuator (air actuator (57) see figure 7) means for operating the valve means to move adjacent portions of the flexible membrane means against and to allow adjacent portions of the flexible membrane means to move away from the associated inlet and outlet ports to respectively close and open the ports (see columns 5-6 lines 53-19), such that when a negative actuating fluid pressure is provided to the flexible membrane means to move the pre-formed flexible means part out of the cavity the first valve means allows the adjacent portion of the flexible membrane means to move away from and open the inlet port and the second valve means moves the adjacent portion of the flexible membrane means against and closes the outlet port so that fluid may be drawn from a reservoir through the inlet port and into the cavity, and such that when a positive actuating fluid pressure is provided to the flexible membrane means to move the preformed part of the flexible membrane means into the cavity the first valve means moves the adjacent portion of the flexible membrane means against and closes the inlet port and the second valve means allows the adjacent portion of the flexible membrane means to move away from and open the outlet port so that fluid is pumped from the cavity and through the outlet port (see figures 8A-8D and columns 6-7 lines 51-40).

In Reference to Claim 55

Danby teaches a disposable pump unit according to claim 54 (see the rejection of claim 54 above) wherein each valve actuator means includes an axially movable armature (piston (51) see figure 7).

In Reference to Claim 57

Danby teaches a disposable pump unit according to claim 55 (see the rejection of claim 55 above), including seals around the armatures of the valve actuator means (The liners (13A and 13B) are welded together throughout the pump to form individual passageways and cells. These welds serve as seals to keep the separate cells airtight, and the seals are formed around the chambers and the valve actuator armatures).

In Reference to Claim 58

Danby teaches a disposable pump unit according to claim 54 (see the rejection of claim 54 above), wherein the reusable pump actuator has a body including a surface with a cavity therein (see figure 3 where the pump bodies (33A and 33B) have cavities for the pump cells and passageways), such that when the reusable pump actuator is coupled to the disposable pump unit and negative and positive actuating fluid pressures are provided the pre-formed part of the flexible membrane means moves into and out of the pump actuator cavity (see columns 6-7 lines 51-40) such that the pumped volume of fluid is defined on one side by the surface of the pump cavity and on the other side by a surface of the pump actuator cavity (The upper half (33A) of the rigid shell serves as the pump actuator since it contains the connections to the high and low pressure reservoirs. Thus the liner (13A and 13B) moves into and out of the lower cavity and the cavity



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associated with the actuators (upper and lower (33A and 33B) portions of the casing) during its pumping stroke, see figure 8A).

In Reference to Claim 59

Danby teaches a disposable pump unit according to claim 58 (see the rejection of claim 58 above), wherein the armature associated with the inlet port extends into a volume defined between the pump actuator cavity (the upper half (33A) of the rigid shell serves as the pump actuator since it contains the connections to the high and low pressure reservoirs) and the flexible membrane means of the disposable pump unit (see figure 7 where the wedge (53) portion of the actuating piston (51) extends into a space between the upper shell (33A) and the top of membrane (13A)).

In Reference to Claim 60

Danby teaches a disposable pump unit according to claim 54 (see the rejection of claim 54 above), wherein the pump actuator includes means (sensors (101) sense the liquid level in the pumping chambers) for detecting the presence or absence of fluid in the disposable pump unit body cavity (see column 7 lines 41-67).

In Reference to Claim 61

Danby teaches a disposable pump unit according to claim 60 (see the rejection of claim 60 above), wherein the detecting means comprises ultrasonic detection means (Danby discloses that the sensors could be optical or ultrasonic, see column 7 lines 41-67).

3. Claims 31 and 37 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent 7,284,966 to Xu et al. (Xu et al.).

In Reference to Claim 31

Xu et al. teach a disposable pump unit for receiving and metering a predetermined volume of fluid (see figure 5), the pump comprising a body (top housing layer (4) and bottom housing layer (6)), the body having a surface at which opens the mouth of a cavity formed in the body (surface that opens to inlet (24)), an inlet port (inlet (24)) for connection with a reservoir of fluid and opening at the body surface adjacent to the mouth of the cavity whereby, when the inlet port is open when the pump is being filled with fluid from the reservoir, fluid can flow from the inlet port into the cavity via the mouth thereof (see figure 5B and column 7 lines 35-52), an outlet port (outlet (26)) for the fluid and opening at the body surface, and a fluid flow passageway extending through the body and connecting the cavity to the outlet port (see figure 5); and flexible membrane (intermediate flexible layer (8)) means sealingly secured at its periphery to the body surface and having a first portion overlying the cavity and the inlet port (leftmost portion of the flexible layer as shown in figure 5 covers the inlet port and the pumping recess (10)) and a second portion overlying the outlet port (the rightmost portion of the flexible layer as shown in figure 5 covers the outlet port), the flexible membrane means whereat it overlies the inlet and outlet ports being moveable against the ports to close the ports (see figure 5 where the valve portions (44) of the flexible layer open and close due to pressure differentials).

In Reference to Claim 37

Xu et al. teach the disposable pump unit according to claim 31 (see the rejection of claim 31 above), wherein the flexible membrane means comprises a layer of polyamide and a layer of polyurethane (Xu et al. teach that the intermediate flexible layer (8) may be made from various compounds, including polyamide and polyurethane. See column 6 lines 42-60. Additionally, Xu et al. teach that the intermediate flexible layer (8) is sandwiched between two rigid housing layers (4, 6) that may be made from polyamide. Thus the membrane of Xu et al. consists of a layer of polyurethane and a layer of polyamide in the sense that it is a single layer of polyurethane sandwiched between two housing layers.).

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 42 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Danby in view of U.S. Patent 3,661,060 to Bowen (Bowen).

In Reference to Claim 42

Danby teaches a disposable pump unit according to claim 34 (see the rejection of claim 34 above), but does not teach the use of a plurality of passageways in the surface of the cavity.

Bowen teaches a similar diaphragm pump (see figure 1) that is reciprocated by an applied pressurized fluid that flows through delivery bores (17). The delivery bores consist of a plurality of passages formed in the surface of the pumping cavity. It would have been obvious to one of ordinary skill in the art at the time of invention to apply the pressurized fluid of Danby via a plurality of bores as taught by Bowen in order to evenly spread the reciprocating pressure across the diaphragm and avoid localized stress and strain. This would also inhibit the formation of occluded regions of fluid between the cavity wall and the flexible membrane means, so that the flexible membrane means comes into contact with substantially the whole surface of the cavity to ensure that substantially all of the fluid flowed into the cavity from the reservoir during filling of the pump is forced out of the cavity, thereby to ensure that a substantially repeatable volume of fluid is dispensed or metered from the pump.

In Reference to Claim 43

Danby as modified by Bowen teaches a disposable pump unit according to claim 42 (see the rejection of claim 42 above), wherein the plurality of passageways comprise a plurality of grooves (The passageways are bores or grooves formed in the pump casing itself).

6. Claims 45 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Danby in view of U.S. Patent 4,936,689 to Federighi et al. (Federighi et al.).

In Reference to Claim 45

Danby et al. teach a disposable pump unit according to claim 44 (see the rejection of claim 44 above), but does not teach the specific details of the mixing chamber (107).

Federighi et al. teach a static mixing device that consists of a conduit (12) with a mixing element (14) inside that defines a tortuous path for fluids flowing through the conduit. This tortuous flow path aids in the mixing of the fluids. It would have been obvious to one of ordinary skill in the art at the time of invention to include a tortuous flow path in the mixing chamber (107) of Danby in order to better mix the fluids flowing through it. The tortuous flow path would be constructed as taught by Federighi et al. by placing several obstructions (segments (14) and plates(30)) in the mixing chambers flow paths.

In Reference to Claim 47

Danby as modified by Federighi et al. teaches a disposable pump unit according to claim 45 (see the rejection of claim 45 above), wherein the mixing means is a static mixer through which an admixture of pumped fluid and diluent flows (The mixing means as taught by Federighi et al. are static, and the mixing chamber of Danby is disclosed as being for mixing a base liquid (e.g.- carbonated water) to dilute a pumped beverage).

7. Claims 50-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Danby in view of U.S. Patent Application Publication 2002/0038392 to De La Hueraga (De La Hueraga).

In Reference to Claim 50

Danby teaches a disposable pump unit according to claim 34 (see the rejection of claim 34 above), including a reusable pump actuator (the pump body (33a and 33b) and the actuator are reusable) for being coupled to the disposable pump unit (the liner (13) is disposable) to provide actuating fluid to operate the disposable pump unit, but does not teach an identification means for providing information about the fluid to be pumped, and reader means for reading information provided by the identification means.

De La Huerga teaches an IV bag or reservoir with a bar code or RFID tag attached to it that can be read by an IV pump (see paragraph [0030]). It would have been obvious to one of ordinary skill in the art at the time of invention to identify the reservoirs of Danby with RFID tags as taught by De La Huerga and to include the RFID reader of De La Huerga so that the contents of the reservoirs can be identified before they are opened or attached to the pump.

In Reference to Claim 51

Danby as modified by De La Huerga teaches a disposable pump unit according to claim 50 (see the rejection of claim 50 above), wherein the identification means is a radio frequency identification (RFID) tag (see paragraph [0030]).

In Reference to Claim 52

Danby as modified by De La Huerga teaches a disposable pump unit according to claim 50 (see the rejection of claim 50 above), wherein the identification means is an Electro-Erasable-Programmable-Read Only Memory (EEPROM) chip (De La Huerga also notes a system where an electronic memory is attached to a reservoir bag, see

paragraph [0016, and the memory can be read to provide information about the bag's contents].).

### ***Conclusion***

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JESSICA L. MYERS whose telephone number is (571)270-5059. The examiner can normally be reached on Monday through Friday, 8:30am to 5:30pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Devon Kramer can be reached on 571-272-7118. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

9. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Devon C Kramer/

Art Unit: 3746

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